Texas A&M University
IRB Protocol Checklist and Application
Protocol for Human Subjects in Research

IRB PROTOCOLS: Submit the original and one copy of the complete IRB protocol (application and required documentation) to the Institutional Review Board, Office of Research Compliance, Centeq Building, 1500 Research Parkway, Suite B150, TAMU 1186, College Station, TX 77843-1186. Review will not begin until all required documentation is received. Applications requiring Full Review must be submitted a minimum of 15 business days before an IRB meeting, depending on workload. For assistance call (979)458-4067 or email irb@tamu.edu. Applications must be typed, single-sided, with pages numbered. Applications, consent documentation, surveys, etc. will not be accepted with spelling, grammatical and/or typographical errors.

CHECKLIST: Please check and attach all items that apply to your research.

☐ Part I: Summary Cover Sheet
☐ Part II: Detailed Study Description
☐ Conflict of Interest Statement (Principal and Co-Investigators)
☐ NIH Training Certificate and ☐ TAMU RCR Training Certificate; or ☐ CITI Training Certificate (Principal and Co-Investigators)
☐ Grant Proposal (if Federally funded)

Informed Consent Document(s) (must contain all elements of consent)

☐ Consent Form
☐ Parental Permission Form
☐ Assent Form (if research involves minors, ages 7-17)
☐ Cover Letter (for mail out surveys)
☐ Information Sheet
☐ Telephone Script (for telephone surveys)
☐ Videotape/Audiotape Release Form (if not included in the consent and/or assent documents)
☐ Justification for Waiver of Consent and/or Signed Consent

Note: If informed consent/assent documents are longer than one page, number each page in the format "page x of y" and blank space for date and initial "Date _____ Initial _____. Page #'s will be separate from IRB Application

☐ Debriefing form (if deception is used)
☐ Survey/Assessment Instruments
☐ Recruitment Media/Newspaper Advertisements
☐ Compensation conditions, schedule of payment
☐ FDA Form 1572 (for investigators involved in drug or biologic studies)
☐ Drug or Device Accountability Record
Texas A&M University
IRB Application
Protocol for Human Subjects in Research

Part I: Summary Cover Sheet

☑ Request for Exemption (Exempt from Full Board Review)
□ Request for review under an Expedited Review Category
□ Request for Full Review

New submission ☑ Re-submission □ (If protocol was disapproved)

Investigator Information
Principal Investigator Name: Gary Wingenbach
Faculty ☑ Staff □ Graduate Student □ Undergraduate Student □
Department ALEC College COALS Mail Stop 2116
Phone (979) 862-1507 Email g-wingenbach@tamu.edu Fax (979) 845-6296
Is this study part of a Thesis or Dissertation? Yes ☑ No □
If Yes, do you have committee approval? Yes ☑ No □

Co-Investigator Name: Clark Springfield
Faculty ☑ Staff □ Graduate Student □ Undergraduate Student □
Department AGEC College COALS Mail Stop 2124
Phone (979) 845-3805 Email hcspringfield@ag.tamu.edu Fax (979) 458-1755

Graduate Committee Chair/Faculty Advisor Name (if student):
Department College Mail Stop
Phone Email Fax

Project Title: Student Involvement in the Clubs of the Department of Agricultural Economics

Funding Status: Funded ☑ Not Funded □ Pending □ (Please attach a copy of Grant Proposal)
Funding Agency: Funding Amount:
Funding Administrator: RF □ TAES □ TEES □ TAMU □ TTI □

Risk Management Matrix

<table>
<thead>
<tr>
<th>Seriousness of Risk</th>
<th>Probability That Something Will Go Wrong</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Likely to occur immediately or in a short period of time, expected to occur frequently</td>
</tr>
<tr>
<td>I - May Result In Death</td>
<td>5</td>
</tr>
<tr>
<td>II - May cause severe injury, major damage or loss, and/or result in negative publicity for the participant(s) involved</td>
<td>5</td>
</tr>
<tr>
<td>III - Participation presents a minimal threat to safety, health and well-being of participant(s)</td>
<td>4</td>
</tr>
<tr>
<td>IV - No more than minimal risk</td>
<td>3</td>
</tr>
</tbody>
</table>

Red Zone – 4 thru 5  Yellow Zone – 2 thru 3  Green Zone – 1
(If your protocol falls in the Red or Yellow Zone, please call (979) 458-4067 for further instructions)

Seriousness of risk IV Probability that something will go wrong 1
Objective Estimate of Risk to Subject:  Low ☒ Medium ☐ High ☐

<table>
<thead>
<tr>
<th>Activity</th>
<th>Associated Risks</th>
<th>Method to Manage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will Existing Documents Be Used? Yes ☒ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will Existing Specimens Be Used? Yes ☒ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Methodology: Qualitative ☐ Quantitative ☒ Both ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender of Subjects: Male ☐ Female ☐ Both ☒</td>
<td></td>
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<tr>
<td>Estimated Age of Subjects: 18 to 25</td>
<td></td>
<td></td>
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<tr>
<td>Location of Research: College Station, TX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Participants: 560</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Subject Recruitment**

**Subjects Recruited From:**
- ☒ Psychology Subject Pool
- ☒ Other Subject Pool AGEC courses
- ☐ Other TAMU Students
- ☐ Community
- ☐ Women/Fetuses
- ☐ Children
- ☐ Prisoners
- ☐ Hospitals
- ☐ Treatment Centers
- ☐ Schools
- ☐ Other ______

**Compensation/Course Credit**

- ☐ Yes ☒ No Compensation for Subjects (If Yes, attach regular payment schedule)
- ☐ Yes ☒ No Research/Course Credit for Subjects

**Deception**

- ☒ Yes ☐ No Deception Used (If Yes, attach debriefing form)

**Invasive or Sensitive Procedures**

- ☒ None used
- ☐ Blood Samples
- ☐ Urine Samples
- ☐ Physical Measurements (electrodes, etc.)
- ☐ Stress Exercise
- ☐ Review of Medical/Psychological Records
- ☐ rDNA
- ☐ Other (specify): ______

**Sensitive Subject Matter**

- ☒ None used
- ☐ Abortion
- ☐ Sexual Activity
- ☐ AIDS/HIV
- ☐ Suicide
- ☐ Alcohol
- ☐ Learning Disability
- ☐ Body-composition
- ☐ Drugs
- ☐ Criminal-activity
- ☐ Depression
- ☐ Psychological Inventory
- ☐ Other (specify): ______

**Provisions for Confidentiality/Anonymity**

- ☒ Replies Coded
- ☒ Secure Storage
- ☐ Anonymous response OR
- ☒ Confidential

(Cannot be both anonymous and confidential)
Consent Documentation
☐ Consent Form    ☐ Parental Permission Form    ☐ Assent Form
☐ Cover Letter    ☐ Information Sheet    ☐ Telephone Script
☐ Videotape and/or Audiotape Release

Location where consent forms will be filed: __________

Note: Consent forms must be kept on file for 3 years after completion of the study.

Request of waiver of consent: Yes ☐ No ☒ Request of waiver of signed consent: Yes ☐ No ☒
If yes to either, attach a justification for waiver request. Criteria for waiver requests can be found in the
Federal regulation 45 CFR 46.116 and 45 CFR 46.117 at the following Web address:

Do you have any relationship with any of the subjects, other than your investigator role? Yes ☐ No ☒
If yes, you must explain the relationship in Part II of the application and clarify how you will avoid any type
of coercion (doctor-patient, teacher-student, counselor-student, etc.).

Other Compliance Issues
If the study involves the use of animals, infectious biohazards, and/or recombinant DNA, it is required that
approval be granted for the use of such through the appropriate compliance committee. This information
may be accessed through the Research Compliance Website at http://researchcompliance.tamu.edu.

This study also involves the use of animals. ☐ Yes ☒ No
If yes, complete the following:
☐ An application has been submitted for review by the University Lab Animal Care Committee.
☐ An application has been reviewed and approved by the University Lab Animal Care Committee.
    AUP Number: ______  Approval Date: ______

This study also involves the use of infectious biohazards or recombinant DNA. ☐ Yes ☒ No
If yes, complete the following:
☐ A registration form has been submitted for review by the Institutional Biosafety Committee.
☐ An approved registration is currently on file with the Institutional Biosafety Committee.
    Registration Number: ______  Approval Date: ______

Abstract
Please provide a brief statement, in lay terminology, outlining the purpose of this study. (Why you are
doing this research project and what you propose to learn.)
To identify factors affecting students' involvement in Department of Agricultural Economics club activities.

The U.S. population is becoming increasingly culturally, linguistically, economically, and
ethnically diverse. The research needs to make a concerted effort to ensure that research subjects
reflect the population demographically, including these groups who have been traditionally under
represented. However, it is recognized that the available pool of subjects may preclude having a
balanced population. If you cannot use a diverse population in your research, you must justify
this action in Part II, A, 1.

For answers to questions regarding the IRB application process, please check with the IRB office
at (979) 458-4067 or irb@tamu.edu. All protocol applications require an original and one (1) copy
of each instrument, i.e., protocol checklist, Part I, Part II (with signatures), Part III, consent
documents, research instrument(s), recruitment materials, training certificates, etc.
REQUEST FOR EXEMPTION (from full IRB review)

45 CFR 46.101(b) - Some research projects involving human subjects are exempt from full review by the IRB. The IRB makes the final decision whether or not a proposal is exempt from full IRB review. If the protocol cannot be reviewed under and exempt category, it will be placed on the next available IRB meeting agenda. (Sensitive topics and subjects such as children or minors, pregnant women and prisoners are not considered for exempt research).

Basis for Exemption (Do not check unless requesting an exemption from full IRB review.)

☐ 45 CFR 46.101(b)(1) - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
☒ 45 CFR 46.101(b)(2) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
☐ 45 CFR 46.101(b)(3) - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☐ 45 CFR 46.101(b)(4) - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
☐ 45 CFR 46.101(b)(5) - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
☐ 45 CFR 46.101(b)(6) - Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

REQUEST FOR EXPEDITED REVIEW UNDER THE FOLLOWING CATEGORIES

45 CFR 46.110 - Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. The IRB makes the final decision whether or not a proposal may be expedited. If the protocol cannot be reviewed under an expedited category, it will be placed on the next available IRB meeting agenda.

Expedited Review Adjunct Categories (Do not check unless requesting expedited review)

☐ 1. Clinical studies of drug and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as described. (a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, 2 considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) ununcannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows: (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) Where no subjects have been enrolled and no additional risks have been identified; or (c) Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. (Note: This category must be pre-approved by the IRB during initial protocol review and approval during a convened meeting.)
Part II: Detailed Study Description

Part A – Protocol Information

1. Selection of Subjects
   a. Source and number: **560 undergraduate students majoring in Agricultural Economics at Texas A&M University**
   b. Method of recruitment and selection: **electronic mail contact through neo email services**
   c. Ages and gender: **male and female ages approximately 18 to 25**
   d. Compensation: **none**
   e. Location and duration of experiment: **complete an online survey, 7 to 10 minutes**
   f. Specific steps to ensure confidentiality or anonymity of responses of results: **Confidential responses are coded and submitted through secure transmissions and storage protocols.**
   g. The investigator’s relationship to subjects: **None**

2. Purpose of study: **To identify factors affecting students’ involvement in departmental club activities.**

3. Research Procedures: **Online survey methods using opinion items with rating scales**
   a. Physical/Behavioral Aspects: **Respond to opinion questions about self-perceptions of departmental club involvement**
   b. Deception or Coercion: **None**

4. Risks and Benefits to Subjects
   a. A description of any potential risks or discomforts to the subject: **None**
   b. A definition of benefits to the research subject or alternatives for participation in the study. **Note: Do not include broad benefits to society or potential research benefits to a group as a benefit to the subjects.** **None**
Part B – Signature Assurance

*Principal Investigator/Graduate Student Assurance Statement

I understand Texas A & M University’s policy concerning research involving human subjects and I certify that:

1. I have read The Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” and subscribe to the principles it contains. In light of this Declaration, I present for the Board’s consideration this application, which will be explained to the subject about the proposed research.
2. I accept responsibility for the scientific and ethical conduct of this research study;
3. I will obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form:
4. I will immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;
5. I will complete, on request by the IRB, the Continuation/Final Review Forms.

SIGNATURE: _______________________________ DATE: _____

TYPED NAME: Gary J. Wingenbach

CO-INVESTIGATOR SIGNATURE: _______________________________ DATE: _____

TYPED NAME: H. Clark Springfield III

*Faculty/Research Advisor’s Assurance Statement

I certify that I have read and agree with this proposal, that the PI has received adequate training to perform this research, and will receive adequate supervision while performing this research.

SIGNATURE: _______________________________ DATE: _____

TYPED NAME: _____

* All investigators must have the signature from the department head for completion of the signature assurance. Undergraduate and graduate students must have faculty/research advisor’s signature in addition to the signature of the department head.

**Department Head

This is to certify that I have reviewed this research protocol and agree that the research activity is within the mission of the Department and appropriate for the responsibilities and assigned duties of the principal investigator.

SIGNATURE: _______________________________ DATE: _____

TYPED NAME: Christine D. Townsend

**If the principal investigator is also the Department Head, the College Dean or equivalent must sign the Signature Assurance Sheet.
CONFLICT OF INTEREST STATEMENT

All Principal Investigators and Co-Investigators must complete a separate Conflict of Interest Statement, and comply with the conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit IRB approval and possible funding. This disclosure must also be updated annually when the IRB protocol is renewed.

Principal Investigator:  **Gary J. Wingenbach**
Co-Investigator:  

Department:  **ALEC**   College:  **COALS**

Phone  **(979) 862-1507**   Email  **g-wingenbach@tamu.edu**   Fax  **(979) 845-6296**

Project Title:  **Student Involvement in the Clubs of the Department of Agricultural Economics**

Funding Agency:  **none**

Funding Administrator:  **RF □  TAES □  TEES □  TAMU □  TTI □**

☐ I have no conflict of interest related to this project.
☐ I have a non-financial conflict of interest related to this project. (If checked, please describe below.)

☐ I have a financial conflict of interest related to this project. (If checked, please provide information regarding the financial interest as described below and as it applies to this project. All items must be marked confidential and provided in a separate envelope or folder.)

   a) The names of affected corporations, both for-profit and not-for-profit, for which the person serves as a member of the governing board in the capacity of a director, advisory director, trustee, or otherwise.
   b) The names of affected corporations for which the person serves as an executive officer.
   c) The name of affected partnerships, limited partnerships, proprietorships, or other business associations of which the person is a partner, joint venture or owner.
   d) The amount of any compensation received for services related to (a), (b), (c), including any benefits, direct or indirect (reported by range of amounts), and benefits received for intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
   e) Affected business entities in which the person holds a controlling interest or is the principal shareholder.
   f) Whether the person is employed by any affected business entities described in (a) through (e) above that have any relationship to Texas A&M University or any of its components, and a brief description of such relationship.

_____________________________________________________ ______________________
Signature of Investigator      Date
(Original signature only – a "per" signature is not acceptable)

IRB Office Use Only